Safety and Efficacy Study of Electrotransfer of Plasmid AMEP to Treat Advanced or Metastatic Melanoma

This study is currently recruiting participants.
Verified by BioAlliance Pharma SA, November 2009

First Received: January 8, 2010 No Changes Posted

Sponsor:	BioAlliance Pharma SA
Information provided by:	BioAlliance Pharma SA
ClinicalTrials.gov Identifier:	NCT01045915

Purpose

The objective of the present trial is to evaluate the tolerability and the safety of the intratumoural electrotransfer of increasing doses of Plasmid **AMEP** in patients suffering from advanced or metastatic melanoma and to identify doses that could be effective in man.

Condition	Intervention	Phase
Melanoma	Biological: naked DNA coding for protein AMEP	Phase I

Study Type: Interventional
Study Design: Control: Dose Comparison
Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Safety and Efficacy of Intratumoural Electrotransfer of Plasmid AMEP in Patients Suffering From Advanced or Metastatic Melanoma: an Open Phase 1 Trial

Resource links provided by NLM:

MedlinePlus related topics: Melanoma

U.S. FDA Resources

Further study details as provided by BioAlliance Pharma SA:

Primary Outcome Measures:

- Determination of Dose Limiting Toxicity defined as any grade 4 clinical, biological or any life-threatening ECG event occurring during the 9 weeks following treatment
  [Time Frame: 9 weeks] [Designated as safety issue: No]

Estimated Enrollment: 18
Study Start Date: December 2009
Estimated Study Completion Date: September 2011
Estimated Primary Completion Date: June 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Plasmid AMEP electrotransfer: Experimental	Biological: naked DNA coding for protein AMEP 2 injections 1 week interval of 4 increasing doses of plasmid with electrotransfer

Detailed Description:

In this open, multicentre, dose escalation study, successive cohorts of 3 patients suffering from advanced or metastatic melanoma will be electrotransferred increasing doses of Plasmid AMEP into cutaneous melanoma lesions in 2 divided doses at one week interval.

Eligibility

Ages Eligible for Study: 18 Years to 75 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Male or non-pregnant, non-breast feeding female;
2. Aged between 18 and 75 years;
3. Stage IIIB, stage IIIC or stage IV melanoma with:
   - At least 2 cutaneous or subcutaneous non necrotic accessible tumours;
   - Tumour size of 1 to 1.5 cm diameter;
   - No minimum distance between the 2 selected lesions;
4. Progressive melanoma not responding to previous treatments or patients refusing other therapies;
5. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2;
6. For women of child-bearing age: effective contraception method (oral contraception or intra-uterine device) used for more than 2 months before the 1st administration and to be maintained for 3 months after the last administration of Plasmid AMEP;
7. Having given a written informed consent.

Exclusion Criteria:

1. Significant cardiac arrhythmias, electronic pacemakers, defibrillators, or any implanted electronic device;
2. Recent (less than 6 months) acute vascular diseases (stroke, MI...);
3. History or treatment of seizures within the last 5 years;
4. Clinically significant abnormality at pre-study full physical examination;
5. Any clinically significant ECG abnormalities;
6. Prior systemic therapy or any other antineoplastic treatments within the last 4 weeks, radiotherapy or surgery unrelated to the fields in question are allowed;
7. Abnormal renal function (creatinine plasma level > ULN);
8. Abnormal liver function tests (any of the following):
   - PT < 70%, ASAT, ALAT, alkaline phosphatases, GGT and/or total bilirubin > ULN in the absence of liver metastasis;
   - PT < 70%, ASAT, ALAT > 2 ULN, alkaline phosphatases > 1.5 ULN, GGT > 5 ULN and/or total bilirubin > 3 ULN in the case of liver metasteses;
9. Abnormal bone marrow function: haemoglobin < 10g/dL, WBC < 3.10⁹ /L and/or platelet count < 100.10³ /L;
10. Clinically significant abnormality in pre-study laboratory tests;
11. Evidence of significant active infection (e.g., pneumonia, wound abscess, etc);
12. Intractable coagulopathy;
13. Any significant disease, including psychiatric and dermatology diseases that may affect the proper evaluation of efficacy or safety;
14. Patients who had participated in another clinical trial in the last 30 days prior to enrolment in the present clinical trial;
15. Patients unwilling or unable to comply with protocol requirements and scheduled visits.

Note: patients with brain metastases, or waiting for other therapies (i.e. isolated limb perfusion) may be included.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01045915

Contacts

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Locations

Denmark

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France

Gustave Roussy Institute — **Not yet recruiting**
Kremlin Bicetre, France, 94805
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Slovenia

Institute of Oncology Ljubljana — **Not yet recruiting**
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Sponsors and Collaborators

BioAlliance Pharma SA

Investigators

Study Director: ATTALI Pierre, MD BioAlliance Pharma

More Information

No publications provided

Responsible Party:	BioAlliance Pharma (Pierre ATTALI, Chief Medical officer)
ClinicalTrials.gov Identifier:	NCT01045915 History of Changes
Other Study ID Numbers:	BA2009/15/01, 2009-013042-88
Study First Received:	January 8, 2010
Last Updated:	January 8, 2010
Health Authority:	France: Afssaps - French Health Products Safety Agency; Denmark: Danish Medicines Agency; Slovenia: Agency for Medicinal Products - Ministry of Health

Keywords provided by BioAlliance Pharma SA:
Stage IIIB, stage IIIC or stage IV melanoma
Progressive melanoma not responding to previous treatments

Additional relevant MeSH terms:

Neuroectodermal Tumors	Neoplasms, Nerve Tissue
Neoplasms	Nevi and Melanomas
Neoplasms by Histologic Type	Neuroendocrine Tumors
Neoplasms, Germ Cell and Embryonal	Melanoma

ClinicalTrials.gov processed this record on June 09, 2010